K002938

SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 2 9 2000

1.0 Submitted By:

Peter Zurlo
Manager, Regulatory Affairs
BECTON DICKINSON CONSUMER HEALTHCARE
1 Becton Drive
Franklin Lakes, NJ 07417-1883
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2.0 Device Name:

B-D 31g x 3/16" (5mm) pen needle

3.0 Predicate Device:

B-D 31g x 5/16" pen needle

4.0 Device Description:

The double-pointed type 304 stainless steel needle is epoxy bonded to a plastic hub (polypropylene) and covered with a plastic needle shield (polyethylene). This needle/hub/shield assembly is placed in a plastic outer container (polyethylene), the open end of which is sealed closed with a laminate seal for subsequent protection. Gamma irradiation sterilization will be employed and the exposed needle hub is screwed onto the Pen injector device. This exposed needle hub will penetrate the rubber septum of an insulin containing cartridge (supplied by others). After the needle shield is removed, it is ready for a subcutaneous insulin injection. The needle assembly is a single-use disposable device.

5.0 Intended Use:

The intended use for the modified device remains the same as the predicate device; for use with a pen injector device for the subcutaneous injection of insulin.

6.0 Technological Characteristics:

The B-D 31g x 3/16" (5mm) pen needle and the predicate device (the B-D 31g x 5/16" (8mm) pen needle) have the same technological characteristics.

SEE ITEM 4 ABOVE FOR A DESCRIPTION

N.B. The only change to the predicate device is to the length of the needle.

7.0 Performance Summary:

The B-D 31g x 3/16" (5mm) pen needle has been bench tested, which included needle pull-out, penetration and insulin injection forces and has proven to function in an equivalent manner as the predicate device.

Based on the results of bench testing the B-D 31g x 3/16" (5mm) pen needle is considered safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Peter Zurlo
Manager of Regulatory Affairs
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K002938
Trade Name: B-D Ultra-Fine III Pen Needle; Model 31 gauge x 3/16"
Regulatory Class: II
Product Code: FMI
Dated: September 19, 2000
Received: September 21, 2000

Dear Mr. Zurlo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002938

Device Name: B-D 31 gauge x 3/16" pen needle

Indications For Use:

The B-D 31 gauge x 3/16" Pen Needle is used with Insulin Pen Injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002938